

**THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

WYETH HOLDINGS CORPORATION,	)	
WYETH-AYERST LEDERLE LLC and	)	
WYETH LLC,	)	
	)	
Plaintiffs and	)	C.A. No. 09-955 (LPS)
Counterclaim Defendants,	)	
	)	
v.	)	
	)	
SANDOZ INC.,	)	
	)	
Defendant and	)	
Counterclaimant.	)	

**PLAINTIFFS' OPENING BRIEF IN SUPPORT OF THEIR  
MOTION TO DISMISS SANDOZ'S FOURTH COUNTERCLAIM AND  
TO STRIKE SANDOZ'S FOURTH AFFIRMATIVE DEFENSE  
DIRECTED TO INEQUITABLE CONDUCT**

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### **NATURE AND STAGE OF THE PROCEEDINGS**

This is an action for patent infringement arising out of Defendant Sandoz Inc.'s ("Sandoz's") filing of Abbreviated New Drug Application ("ANDA") No. 91-620 with the United States Food and Drug Administration ("FDA") for a generic version of Wyeth's antibiotic Tygacil®. Wyeth markets and sells Tygacil®, which is protected by U.S. Patent No. RE40,183 ("the '183 patent") and U.S. Patent No. 7,879,828 (the "'828 patent"), both of which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations listing (the "Orange Book"). The '183 patent claims various compounds, including tigecycline, and the '828 patent claims specific tigecycline formulations containing certain ratios of tigecycline to lactose and an acid to achieve specified pH ranges.

On November 2, 2009, Plaintiffs received a Paragraph IV Notice Letter from Sandoz stating that it had filed ANDA No. 91-620 seeking to manufacture a generic tigecycline product and had certified to the FDA that the '183 patent is invalid, unenforceable and/or will not be infringed by Sandoz's manufacture of its generic tigecycline product. (D.I. 1 at ¶ 12.) On December 11, 2009, Plaintiffs filed this action alleging that Sandoz has infringed the '183 patent. (D.I. 1.) The '828 patent issued on February 1, 2011, and was subsequently listed in the Orange Book in connection with Tygacil®. Sandoz stipulated to infringement of both the '183 and '828 patents on July 14, 2011, and the Court entered the stipulation on July 18, 2011. (D.I. 40.) On August 1, 2011, Plaintiffs received a second Paragraph IV Notice Letter from Sandoz stating that it had amended ANDA No. 91-620 and had certified to the FDA that the '828 patent is invalid, unenforceable and/or will not be infringed by Sandoz's manufacture of its generic tigecycline product. (D.I. 48 at ¶ 21.) On September 7, 2011, Plaintiffs filed an amended and supplemental complaint alleging that Sandoz has infringed both the '183 and '828 patents. (D.I. 48.)

On September 30, 2011, Sandoz answered the amended and supplemental complaint and asserted only invalidity affirmative defenses and counterclaims against Plaintiffs. (D.I. 57.) Fact discovery closed on October 19, 2011. (D.I. 59). Sandoz amended its answer two days later, on October 21, 2011, to include a Fourth Affirmative Defense and Fourth Counterclaim for unenforceability of the '828 patent on the ground of inequitable conduct before the United States Patent and Trademark Office ("PTO"). (D.I. 62.) Plaintiffs have moved to dismiss Sandoz's Fourth Counterclaim and Fourth Affirmative Defense. This is Plaintiffs' Opening Brief in support of that motion.

### **SUMMARY OF ARGUMENT**

1. Sandoz's Fourth Counterclaim should be dismissed with prejudice because Sandoz's allegations, even if taken as true, fail to establish that the applicants acted with "the specific intent to deceive the PTO." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011). Not only does Sandoz fail even to use the word "intent" in its Fourth Counterclaim, Sandoz did not plead any facts that would allow the Court to conclude that the single most reasonable inference from the applicants' alleged conduct is that the applicants had the specific intent to deceive the PTO. In fact, Sandoz's allegations include objective indicators of candor and good faith on the part of the applicants. Sandoz's pleading fails because there can be no finding of intent on the facts alleged.

2. Sandoz's Fourth Counterclaim should be dismissed with prejudice because it does not establish but-for materiality of any alleged omission. Under the *Therasense* materiality standard, a pleading of inequitable conduct requires factual allegations that make it plausible that but for the alleged omission, the Examiner would not have issued the patent. *Therasense*, 649 F.3d at 1291, 1295. All of the references included in Sandoz's Fourth

Counterclaim were admittedly before the Examiner during prosecution of the '828 patent and were the subject of discussion between the applicants and the Examiner.

3. Sandoz's Fourth Counterclaim should be dismissed with prejudice because Sandoz does not allege that the applicants engaged in any affirmative egregious misconduct that could lead to a finding of materiality. The fact that the applicants advocated for particular interpretations of certain prior art references does not establish that the applicants' advocacy was incorrect, let alone that they engaged in any act of egregious misconduct. Sandoz's allegations amount to nothing more than an argument that Sandoz would have presented the prior art in a different light, and should be rejected.

4. Finally, Sandoz's Fourth Affirmative Defense of inequitable conduct, which mirrors the above counterclaim, should be stricken for the same reasons the Fourth Counterclaim should be dismissed. *See, e.g., Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, Civ. No. 08-309-JJF-LPS, 2009 WL 4928024, at \*8-10 (D. Del. Dec. 18, 2009) (recommending striking two affirmative defenses that mirrored two counterclaims for inequitable conduct that were being dismissed for having been insufficiently pled).

#### **STATEMENT OF FACTS**

The '828 patent, entitled "Tigecycline Compositions And Methods Of Preparation," is directed to tigecycline compositions (containing lactose and an acid) that exhibit improved stability in both solid and solution states. The '828 patent was filed on March 13, 2006. The patent claims priority to a provisional application filed on March 14, 2005. (D.I. 62, Ex. 5 at 1.)

The Examiner initially rejected the claims of the '828 patent as obvious in light of U.S. Patent Publication No. 2005/0148553 entitled "Use Of Tigecycline, Alone, Or In Combination With Rifampin To Treat Osteomyelitis And/Or Septic Arthritis" ("Testa") and applicants' admissions of prior art. (D.I. 62, Ex. 3 at 4-5.) Testa disclosed a composition comprising

tigecycline and various excipients including lactose. (D.I. 62, Ex. 3 at 4.) The Examiner found that while Testa failed to disclose the composition with an acid or in a lyophilized form, it would have been obvious to a person of ordinary skill in the art to lyophilize the composition and to add hydrochloric acid to adjust the pH of the composition. (D.I. 62, Ex. 3 at 4-5.)

On September 16, 2010, the Examiner held an interview with Wyeth representatives Christian Ofslager, David Joran and Yi (Ian) Liu. (D.I. 62, Ex. 4 at 2.) During the interview, these representatives presented a slide presentation in support of the applicants' non-obviousness arguments. (D.I. 62, Ex. 3, Ex. 4 at 2.) The presentation sought to distinguish the Testa reference and set forth the unexpected results obtained by the claimed compositions. (D.I. 62, Ex. 3.) The presentation also contained a citation to a prior art European patent application, EP 1,645,277 A1 ("the '277 reference"), and reproduced a figure from the patent application which showed the '277 patentee's interpretation of how lactose stabilizes the non-antibiotic compound tetrodotoxin. (D.I. 62, Ex. 3 at 10.) The '277 reference is listed among the "References Cited" on the cover of the '828 patent and a full copy of the reference appears in the '828 file history. (D.I. 62, Ex. 5 at 1.) The Examiner's summary of the interview states:

Applicant's unexpectedly found that the introduction of lactose reduces the epimerization of tigecycline so that it can be stable and stored for longer period of time. Examiner informed the Applicant that typically unexpected results must translate to real world utility, such as therapeutic effectiveness or in this case stability and storage after reconstitution. . . . [I]t is recommended for the Applicant to submit a Declaration showing any and all relevant data with a statement as to why the claimed invention is unexpected or surprising and how it relates to any real world use.

(D.I. 62, Ex. 4 at 4.)

In response, the applicants submitted an Amendment and Response dated October 5, 2010 as well as the Declaration of Christian Ofslager. (D.I. 62, Ex. 1.) Citing both data from the patent specification and data from FDA submissions that were also submitted to the PTO, the

applicants showed that the addition of lactose to the claimed compositions had the unexpected ability to reduce epimerization, even at reduced pH levels, thus increasing stability and consequently storage times of the compositions in both lyophilized and solution forms. (D.I. 62, Ex. 1 at 1-10.)

In a Notice Of Allowability dated December 6, 2010, the patent Examiner allowed the claims finding that the applicants had overcome Testa, which was “the closest prior art” to the claimed invention. (D.I. 62, Ex. 6 at 7.) The Examiner stated that “the claimed composition unexpectedly reduces the unwanted epimerization and thus stabilizes tigecycline. . . . This unexpected stabilization effect against epimerization introduced by the claimed combination increases the storage time for tigecycline in both lyophilized powder and solutions.” (D.I. 62, Ex. 6 at 8.)

Sandoz’s Amended Answer, Affirmative Defenses, and Amended Counterclaims (“Amended Answer”) included a new counterclaim and affirmative defense of unenforceability of the ‘828 patent due to inequitable conduct based on these proceedings before the PTO, which Wyeth now moves to dismiss and strike. (D.I. 62 at 8-22.)

## **ARGUMENT**

### **I. LEGAL STANDARDS**

#### **A. Motion to Dismiss**

Rule 12(b)(6) permits a party to move to dismiss all or part of an action for “failure to state a claim upon which relief can be granted.” FED. R. CIV. P. 12(b)(6); *LG Elecs. U.S.A., Inc. v. WhirlPool Corp.*, No. 08-234 (GMS), 2009 WL 3738306, at \*1 (D. Del. Nov. 9, 2009). To survive a motion to dismiss, the claimant must raise a right to relief “above the speculative level.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

A claimant’s “obligations to provide the grounds of his entitlement to relief requires more



than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Twombly*, 550 U.S. at 555 (internal quotes omitted). The claimant is required to make a ‘showing’ rather than a blanket assertion of entitlement to relief. *Id.* at 547, 570 (counterclaim-plaintiff must allege “enough facts to state a claim to relief that is plausible on its face”); *LG Elecs.*, 2009 WL 3738306 at \*1. “While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations. When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief.” *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S. Ct. 1937, 1950 (2009); *LG Elecs.*, 2009 WL 3738306, at \*1. If they do not, the court should dismiss the complaint. *LG Elecs.*, 2009 WL 3738306, at \*1.

#### **B. Motion to Strike**

Under Rule 12(f), the Court “may strike from a pleading any insufficient defense or any redundant, immaterial, impertinent, or scandalous matter.” FED. R. CIV. P. 12(f). In deciding a motion to strike, the Court should strike inadequately pled affirmative defenses, particularly where a corresponding counterclaim is dismissed under Rule 12(b)(6). *See, e.g., Power Integrations, Inc.*, 2009 WL 4928024, at \*8-10 (recommending striking two affirmative defenses that mirrored two counterclaims for inequitable conduct that were being dismissed for having been insufficiently pled).

#### **C. Inequitable Conduct**

The law of the Federal Circuit, not the law of the regional circuit, controls the pleading standards for inequitable conduct. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326 (Fed. Cir. 2009). Inequitable conduct must be pled with particularity under Fed. R. Civ. P. 9(b). *See id.* The allegations must identify the “specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO.” *Id.* at 1327. The “pleadings

must allege facts giving rise to a reasonable inference of scienter, including both (1) knowledge of the withheld material information or of the falsity of the material misrepresentation, and (2) specific intent to deceive the PTO.” *Softview LLC v. Apple, Inc.*, No. 10-389-LPS, 2011 WL 4571793, at \*1 (D. Del. Sept. 30 2011) (*quoting Exergen*, 575 F.3d at 1330) (internal quotes omitted). Although *Exergen* concerned a motion for leave to amend, it applies with equal force to the sufficiency of a pleading that is challenged in a motion to dismiss. See *In re BP Lubricants USA, Inc.*, 637 F.3d 1307, 1311 (Fed. Cir. 2011).

District courts are encouraged to identify deficiencies in a complaint “at the point of minimum expenditure of time and money by the parties and the court,” *i.e.*, at the pleading stage. *Twombly*, 550 U.S. at 558 (citations omitted). Moreover, in the context of charges of inequitable conduct, the enhanced pleading standards are intended to cabin the aggressive overuse of inequitable conduct allegations, thereby “protecting the reputations of those who would be harmed by such charges; preventing the use of inequitable conduct as a litigation tactic; and shielding the courts, patent system, and public from the burden created when such claims are brought on slender grounds.” See *Schwendimann v. Arkwright Advanced Coating, Inc.*, No. 11-820, 2011 WL 4007334, \*4 (D. Minn. Sept. 8, 2011); *Exergen*, 575 F.3d at 1331; *Therasense*, 649 F.3d at 1289-90.

The Federal Circuit recently refined and tightened the pleading requirements for inequitable conduct by clarifying that “materiality” and “intent to deceive” are two separate and distinct requirements of an inequitable conduct charge and that both must be present to establish inequitable conduct. *Therasense*, 649 F.3d at 1287, 1290. In other words, the accused infringer must show that the applicants “misrepresented or omitted material information with the specific intent to deceive the PTO.” *Therasense*, 649 F.3d at 1287. “District courts ‘should not use a

‘sliding scale,’ where a weak showing of intent may be found sufficient based on a strong showing of materiality, or visa versa.” *Linear Tech. Corp. v. Monolithic Power Sys. Inc.*, No. 06-476-GMS, 2011 WL 4014467, at \*6 (D. Del. Nov. 9, 2009) (quoting *Therasense*, 649 F.3d at 1290). The burden to present facts to establish both intent and materiality rests entirely on Sandoz, as the party alleging inequitable conduct. *Therasense*, 649 F.3d at 1291.

First, Sandoz must plead facts to show that the applicants “acted with the specific intent to deceive the PTO.” *Therasense*, 649 F.3d at 1290. “[F]inding that the misrepresentation or omission amounts to gross negligence or negligence under a ‘should have known’ standard does not satisfy this intent requirement.” *Id.* (quoting *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988)). In the case of an omission, Sandoz must set forth sufficient facts from which to infer that the applicants “knew of the reference, knew that it was material, and made a deliberate decision to withhold it.” *Therasense*, 649 F.3d at 1290. The Court can not “infer intent solely from materiality.” *Id.* Rather, it must consider intent to deceive independent of its analysis of materiality. *Id.* Intent can be inferred from circumstantial facts, but must ultimately be “the single most reasonable inference.” *Id.* (quoting *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008)).

Second, in the case of any alleged omission, Sandoz must plead facts showing that “the PTO would not have allowed a claim had it been aware of the undisclosed prior art.” *Therasense*, 649 F.3d at 1291. Under the *Therasense* materiality standard, a pleading of inequitable conduct requires factual allegations that make it plausible that but for the alleged omission, the Examiner would not have issued the patent. *Id.* at 1291, 1295.

Although the but-for materiality standard applies to alleged omissions, the Federal Circuit “recognizes an exception in cases of affirmative egregious misconduct.” *Id.* at 1292. In order to

fall within this rare exception to the general “but for” test for materiality, the alleged infringer must plead facts to show that “the patentee has engaged in affirmative acts of misconduct, such as the filing of an unmistakably false affidavit.” *Id.*

## **II. SANDOZ’S FOURTH COUNTERCLAIM SHOULD BE DISMISSED**

Sandoz’s inequitable conduct allegations do not meet the pleading requirements dictated by *Exergen* under the law of *Therasense*. To prevail on a claim of inequitable conduct, Sandoz must plead facts showing “that [the applicants] misrepresented or omitted material information with the specific intent to deceive the PTO.” *Therasense*, 649 F.3d at 1287. Sandoz has failed to allege with sufficient particularity either of these elements. Although Sandoz filled no less than ten of its 24-page pleading attempting to support its inequitable conduct claim (*see* D.I. 62), Sandoz’s inequitable conduct claim is critically deficient and should be dismissed. Moreover, because Sandoz asserted its Fourth Counterclaim after the close of discovery, no further facts exist to support its claims. Plaintiffs’ motion to dismiss should, thus, be granted with prejudice.

### **A. Sandoz Failed to Plead Any Fact Showing An Intent To Deceive**

Sandoz’s counterclaim for unenforceability does not contain *any* allegation concerning an alleged intent to deceive the PTO. Sandoz named three individuals in its Fourth Counterclaim: a Wyeth employee (Christian Ofslager), and two attorneys responsible for the prosecution of the ‘828 patent (Ian Liu and David Joran). However, Sandoz does not allege any facts to establish an intent to deceive the PTO by any of these individuals. Indeed, Sandoz does not even use the word “intent” a single time in its counterclaim. (*See* D.I. 62 at ¶¶ 4-33.) Nor are there any facts from which the Court could infer an intent to deceive the PTO by any of the three named individuals. (*See id.*) Sandoz’s failure to address the intent of any person involved in the prosecution of the ‘828 patent requires dismissal of their inequitable conduct claim, with prejudice.

First, Sandoz's allegations are deficient because they do not plausibly suggest any deliberate decision by any person to mischaracterize a reference or omit information. *Exergen*, 575 F.3d at 1331. As in *Exergen*, Sandoz has not alleged facts that show a particular individual had knowledge of specific information that is alleged to be material, *let alone* that this individual then made a deliberate decision to withhold it from or falsify information to the PTO.

Second, Sandoz's allegations are deficient because Sandoz does not allege facts from which the Court could conclude that the "single most reasonable inference" to be drawn is that Wyeth intended to deceive the PTO. *Therasense*, 649 F.3d at 1290 (*quoting Star Scientific*, 537 F.3d at 1366); *Exergen*, 575 F.3d at 1329 n.5. In other words, intent to deceive is not legally established when a conclusion that someone did not intend to deceive is as plausible as a conclusion that the person intended to deceive. *See, e.g., Scanner Techs. Corp. v. ICOS Vision Sys. Corp.*, 528 F.3d 1365, 1376 (Fed. Cir. 2008)<sup>1</sup> ("[T]he district court erred when it adopted an unfavorable inference . . . over an equally reasonable favorable inference.").

Where, as here, "there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found." *Therasense*, 649 F.3d at 1290-91. Sandoz's allegations are utterly lacking in any facts to support an inference of an intent to deceive. Thus, a conclusion that the named individuals acted innocently without any intent to deceive the PTO is at least as plausible, if not more so, than a conclusion of intent to deceive.

Moreover, Sandoz's allegations include objective indicators of candor and good faith that make an inference of intent to deceive unreasonable. For example, Sandoz alleged that the three named individuals misconstrued the '277 reference during an interview with the Examiner, but

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<sup>1</sup> While *Scanner Techs* was decided prior to the Federal Circuit's decision in *Therasense*, the Court in *Therasense* adopted the most reasonable inference standard of intent articulated in *Scanner Techs*. *Therasense*, 649 F.3d at 1291-92.

admitted that the ‘277 reference was considered by the Examiner during prosecution of the ‘828 patent. (D.I. 62 at ¶¶ 9-10.) The fact that the ‘277 reference was disclosed during prosecution of the ‘828 patent indicates that the applicants were acting in good faith towards the PTO.<sup>2</sup>

During an interview with the Examiner, the applicants presented their view that the ‘277 reference taught away from the invention of the ‘828 patent. (D.I. 62 at ¶ 10.) As demonstrated in the Examiner’s summary of the interview, the Examiner considered the applicants’ interpretation of the ‘277 reference and stated that another search of the prior art should be conducted “to see if lactose has been used as a stabilizer for [the claimed] substrates.” (D.I. 62, Ex. 4 at 4.) Rather than suggesting an intent to deceive the PTO, this reflects nothing more than the typical exchanges between an applicant and the PTO concerning the proper application and relevance of prior art to the pending application. Sandoz’s allegations suggest nothing to the contrary.

Sandoz’s allegations fail to provide any factual basis for its assertion of inequitable conduct, and the Court should not “infer facts to support a claim that must be pled with particularity.” *Exergen*, 575 F.3d at 1328 (*quoting Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys. LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003)). Moreover, Sandoz asserted its inequitable conduct defense after the close of discovery, so there are no additional facts to which Sandoz could cite to cure this deficiency. Because Sandoz has not and cannot meet its burden of adequately pleading intent, its inequitable conduct claim should be dismissed with prejudice.

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<sup>2</sup> Similarly, Sandoz admitted that *all* of the references included in Sandoz’s counterclaim were submitted to the PTO during the prosecution of the ‘828 patent. (D.I. 62 at ¶¶ 10, 15, 17, 18-21, 23, 25-26, 29.)

**B. Sandoz Failed to Establish But-For Materiality Of Any Alleged Omission**

Sandoz has also failed to establish that any of the alleged omissions were “but for” material to the patentability of the ‘828 patent. Sandoz has the burden of pleading facts sufficient to demonstrate that “the PTO would not have allowed a claim had [the Examiner] been aware” of the alleged omission. *See Therasense*, 649 F.3d at 1291. Not only do Sandoz’s allegations fall short of this standard, the facts pled by Sandoz confirm that all of the prior art Sandoz identified in its pleading were before the Examiner during prosecution of the ‘828 patent.

Sandoz alleges that the applicants committed inequitable conduct by omitting “critical information” concerning data reported in slides addressing stabilization and epimerization rates. To the extent Sandoz intended to allege that this “critical information” was an “omission” under the *Therasense* standard, this allegation fails to meet *Therasense*’s materiality standard. Sandoz did not claim that the so-called “critical information” was material, let alone but-for material. (D.I. 62 at ¶¶ 15-17.) Once again, Sandoz’s own allegations show that Mr. Ofslager “represented to the Examiner” the results of the studies by stating his interpretation of the data. (D.I. 62 at ¶ 15; *see also* D.I. 62 at ¶ 17.) Tellingly, Sandoz did not allege that the applicants withheld any references from the PTO. The Examiner admittedly had all the relevant data and was free to disregard Mr. Ofslager’s interpretation of it and draw his own conclusions.

Sandoz never alleged that “the PTO would not have allowed a claim had [the Examiner] been aware” of the alleged “critical information.” *See Therasense*, 649 F.3d at 1291. Sandoz’s failure to plead properly materiality of any alleged omission provides a second basis upon which the Court should dismiss with prejudice Sandoz’s Fourth Counterclaim.

**C. Sandoz Failed to Establish Or Allege Any Affirmative Egregious Misconduct**

Although Sandoz’s pleading does not clearly establish which information was allegedly omitted and which was allegedly mischaracterized, the remainder of Sandoz’s arguments appear

to be allegations of mischaracterizations of art that was before the Examiner during the prosecution of the '828 patent. However, Sandoz does not allege that there were any "affirmative acts of egregious misconduct," and therefore fails to establish materiality of the alleged mischaracterizations. *Therasense*, 649 F.3d at 1292.

Sandoz first alleged that the applicants mischaracterized the '277 reference, but never asserted that any alleged mischaracterization was material, let alone "egregious" or "unmistakably false." (D.I. 62 at ¶¶ 9-14.) Sandoz's own allegations show that the applicants were merely presenting their opinion that the '277 reference taught away from the claimed inventions of the '828 patent, and that the Examiner assessed those opinions in the normal course of the prosecution. (*See supra* at 10-11.) This type of advocacy by applicants is entirely appropriate; the Examiner was free to assess the '277 reference and the arguments made concerning its teachings.

Sandoz next alleged that the declaration of Mr. Ofslager contains "inaccurate and deceptive" characterizations of the data reported in the patent application and in FDA reports also submitted to the PTO, (D.I. 62 at ¶¶ 18-25), but again does not and cannot establish that the declaration was "unmistakably false." *Therasense*, 649 F.3d at 1292. Sandoz's allegations concerning inconsistencies between the various studies submitted to the PTO completely ignored the larger point that Mr. Ofslager explained in his declaration to the PTO. Specifically, Mr. Ofslager pointed out the unexpected discovery that "at acidic pHs, the addition of lactose reduces the epimer level" significantly when compared (within the same study) to tigecycline stored without lactose. (D.I. 62, Ex. 1 at ¶ 24.) There was nothing false about Mr. Ofslager's declaration or the explanations he provided to the Examiner. Sandoz does not allege otherwise, thereby failing to establish materiality. *See Therasense*, 649 F.3d at 1292.



Sandoz's final allegation relates to two reports and supporting data that were submitted to the FDA and later to the PTO. (See D.I. 62 at ¶¶ 26-30.) Mr. Ofslager identified these reports as further evidence that the addition of lactose to tigecycline led to the unexpected result of stabilizing tigecycline. (D.I. 62, Ex. 1 at ¶¶ 25-26, 28.) Sandoz's counterclaim criticized Mr. Ofslager's alleged failure to highlight the differences between the epimer values across different studies, but did not allege facts showing that the alleged failure was an "affirmative act of egregious misconduct." See *Therasense*, 649 F.3d at 1292. The fact that the Examiner ultimately agreed with Mr. Ofslager's interpretation does not mean he was deceived, or that Mr. Ofslager's declaration contained any false information, let alone that which rose to the level of egregious misconduct.

Sandoz again failed to plead any facts to suggest that any conduct here could fall within the exception to the but-for materiality standard of *Therasense*. Because Sandoz failed to plead facts showing any "affirmative egregious misconduct" or any "unmistakably false affidavit," Sandoz has failed to establish materiality and its Fourth Counterclaim should be dismissed with prejudice.


### **III. SANDOZ'S FOURTH AFFIRMATIVE DEFENSE SHOULD BE STRICKEN**

Sandoz's Fourth Affirmative Defense corresponds to its Fourth Counterclaim. (D.I. 62, compare pp. 8-17, ¶¶ 4-33 to ¶¶ 67-69.) For all of the reasons set forth above with respect to Sandoz's Fourth Counterclaim, this affirmative defense should be stricken because Sandoz has failed to properly allege inequitable conduct. This defense should also be stricken because the corresponding mirror counterclaim is subject to dismissal under Fed. R. Civ. P. 12(b)(6). See, e.g., *Power Integrations, Inc.*, 2009 WL 4928024, at \*8-10 (recommending striking two affirmative defenses that mirrored two counterclaims for inequitable conduct that were being dismissed for having been insufficiently pled).

**CONCLUSION**

For the foregoing reasons, Plaintiffs respectfully request that the Court issue an Order dismissing with prejudice Sandoz's Fourth Counterclaim and striking Sandoz's Fourth Affirmative Defense.

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**CERTIFICATE OF SERVICE**

I hereby certify that on November 7, 2011, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to:

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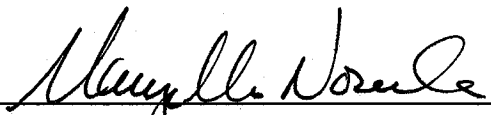
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